

CLAIMS:

1. A system for reducing the cross-sectional surface area of a stent assembly comprising:
 a stent contracting assembly, the stent contracting assembly comprising a
 5 plurality of moveable contracting members, each of the contracting members having a predetermined shape, at least one of the contracting members having a different predetermined shape than the predetermined shape of each of the other contracting members, the plurality of contracting members defining a cross-sectional surface area reduction chamber, the chamber having a reduced cross-sectional surface area configuration
 10 and a pre-reduction cross-sectional surface area configuration, the contracting assembly constructed and arranged to receive at least a portion of a stent assembly into the chamber, wherein when the chamber is in the pre-reduction cross-sectional surface area configuration the at least a portion of the stent assembly has a first cross-sectional surface area and when the chamber is in the reduced cross-sectional surface area configuration the at least a
 15 portion of the stent assembly has a second cross-sectional surface area, the second cross-sectional surface area being less than the first cross-sectional surface area.
2. The system of claim 1 wherein the predetermined shape of the contracting members is substantially rectangular.
3. The system of claim 2 wherein a stent assembly engagement surface of the at least
 20 one of the contracting members defines a stair-step area.
4. The system of claim 1 further comprising a first mandrel, a portion of the first mandrel constructed and arranged to be positioned within the cross-sectional surface area reduction chamber, a first portion of the stent assembly disposed about the portion of the first mandrel.
- 25 5. The system of claim 4 wherein the portion of the first mandrel is expandable from an unexpanded first mandrel diameter to an expanded first mandrel diameter, the expanded first mandrel diameter being greater than the unexpanded first mandrel diameter.
6. The system of claim 5 wherein when the cross-sectional surface area reducing chamber is in the reduced cross-sectional surface area configuration the first mandrel is

positioned within the cross-sectional surface area reducing chamber and the portion of the first mandrel is expanded to the expanded first mandrel diameter.

7. The system of claim 5 wherein when the stent assembly is in the second cross-sectional surface area, the portion of the first mandrel is expanded to the expanded first
5 mandrel diameter.

8. The system of claim 4 further comprising a second mandrel, a portion of the second mandrel constructed and arranged to be positioned within the cross-sectional surface area reduction chamber, a second portion of the stent assembly disposed about the portion of the second mandrel.

10 9. The system of claim 8 wherein the portion of the second mandrel is expandable from an unexpanded second mandrel diameter to an expanded second mandrel diameter, the expanded second mandrel diameter being greater than the unexpanded second mandrel diameter.

10. The system of claim 9 wherein when the cross-sectional surface area reducing
15 chamber is in the reduced cross-sectional surface area configuration the second mandrel is positioned within the cross-sectional surface area reducing chamber and the portion of the second mandrel is expanded to the expanded second mandrel diameter.

11. The system of claim 9 wherein when the stent assembly is in the second cross-sectional surface area, the portion of the second mandrel is expanded to the expanded
20 second mandrel diameter.

12. The system of claim 5 wherein the portion of the first mandrel comprises an expandable balloon.

13. The system of claim 5 wherein at least the portion of the first mandrel is at least partially constructed from an electro-active polymer.

25 14. The system of claim 5 wherein at least the portion of the first mandrel is constructed from one or more layers of the group of layers consisting of: a conductive layer, a proton exchange layer, a carbon nanotube layer, and an elastic layer and any combination thereof.

15. The system of claim 5 wherein at least the portion of the first mandrel is constructed from a plurality of layers, the plurality of layers comprising: a conductive layer, a proton
30 exchange layer, a carbon nanotube layer and an elastic membrane layer.

16. The system of claim 9 wherein the portion of the second mandrel comprises an expandable balloon.
17. The system of claim 9 wherein at least the portion of the second mandrel is at least partially constructed from an electro-active polymer.
- 5 18. The system of claim 9 wherein at least the portion of the second mandrel is constructed from one or more layers of the group of layers consisting of: a conductive layer, a proton exchange layer, a carbon nanotube layer, and an elastic layer and any combination thereof.
19. The system of claim 9 wherein at least the portion of the second mandrel is
10 constructed from a plurality of layers, the plurality of layers comprising: a conductive layer, a proton exchange layer, a carbon nanotube layer and an elastic membrane layer.
20. The system of claim 1 further comprising a second stent contracting assembly, the second stent contracting assembly comprising a plurality of moveable contracting members, the plurality of contracting members of the second stent contracting assembly defining a
15 cross-sectional surface area reduction chamber of the second stent contracting assembly, the chamber of the second stent contracting assembly having a reduced cross-sectional surface area configuration and a pre-reduction cross-sectional surface area configuration, the second stent contracting assembly constructed and arranged to receive the stent assembly into the chamber, wherein when the chamber of the second stent contracting assembly is in the pre-
20 reduction cross-sectional surface area configuration a proximal portion of the stent assembly has a first cross-sectional surface area and when the chamber of the second stent contracting assembly is in the reduced cross-sectional surface area configuration the proximal portion of the stent assembly has a second cross-sectional surface area, the second cross-sectional surface area being less than the first cross-sectional surface area.
- 25 21. The system of claim 20 wherein when the chamber of the second stent contracting assembly is in the pre-reduction cross-sectional surface area configuration or the reduced cross-sectional surface area configuration the cross-sectional surface area of a distal portion of the stent assembly is substantially the same.
22. The system of claim 1 further comprising a protective sheath, the protective sheath
30 constructed and arranged to be positioned within the cross-sectional surface area reduction

chamber, the protective sheath disposed about the stent assembly.

23. The system of claim 22 wherein the protective sheath comprises a wall thickness and an inside surface, the inside surface being defined by a wall thickness pattern, the wall thickness pattern comprising alternating thicker portions of the wall thickness and thinner portions of the wall thickness, the thicker portions extending radially inward toward the stent assembly to a greater extent than the thinner portions, a thinner portion being positioned between each thicker portion.

24. The system of claim 23 wherein the protective sheath further comprises a proximal region and a distal region, the inside surface of the proximal region having a pattern of alternating thicker portions of the wall thickness and thinner portions of the wall thickness that is different than the pattern of the distal region.

25. The system of claim 24 wherein the wall thickness pattern of the proximal region of the inner surface of the protective sheath comprises a thinner portion having a greater circumferential length than each of the other thinner portions.

26. The system of claim 24 wherein the protective sheath is at least partially constructed of urethane.

27. The system of claim 26 wherein the protective sheath is formed by extrusion or inject molding.

28. The system of claim 23 wherein the inside surface of the protective sheath comprises at least one therapeutic agent, the at least one therapeutic agent constructed and arranged to be transferred to the at least a portion of the stent assembly when the chamber is in the reduced cross-sectional surface area configuration.

29. The system of claim 28 wherein the at least one therapeutic agent is at least one non-genetic therapeutic agent selected from at least one member of the group consisting of: anti-thrombogenic agents such as heparin, heparin derivatives, urokinase, and PPACK (dextrophenylalanine proline arginine chloromethylketone); anti-proliferative agents such as enoxaprin, angiopeptin, monoclonal antibodies capable of blocking smooth muscle cell proliferation, hirudin, and acetylsalicylic acid; anti-inflammatory agents such as dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, and mesalamine; antineoplastic/antiproliferative/anti-miotic agents such as paclitaxel, 5-

- fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and thymidine kinase inhibitors; anesthetic agents such as lidocaine, bupivacaine and ropivacaine; anti-coagulants such as D-Phe-Pro-Arg chloromethyl keton, an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-
- 5 thrombin antibodies, anti-platelet receptor antibodies, aspirin, prostaglandin inhibitors, platelet inhibitors and tick antiplatelet peptides; vascular cell growth promoters such as growth factor inhibitors, growth factor receptor antagonists, transcriptional activators, and translational promoters, vascular cell growth inhibitors such as growth factor inhibitors, growth factor receptor antagonists, transcriptional repressors, translational repressors,
- 10 replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin; bifunctional molecules consisting of an antibody and a cytotoxin; cholesterol-lowering agents; vasodilating agents; and agents which interfere with endogenous vasoactive mechanisms, and any combinations thereof.
- 15 30. The system of claim 28 wherein the at least one therapeutic agent is at least one genetic therapeutic agent selected from at least one member of the group consisting of: anti-sense DNA and RNA; DNA coding for anti-sense RNA, tRNA or rRNA to replace defective or deficient endogenous molecules; angiogenic factors including growth factors such as acidic and basic fibroblast growth factors, vascular endothelial growth factor,
- 20 epidermal growth factor, transforming growth factor α and β , platelet-derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor α , hepatocyte growth factor and insulin like growth factor; cell cycle inhibitors including CD inhibitors, thymidine kinase ("TK") and other agents useful for interfering with cell proliferation; at least one of the family of bone morphogenic proteins ("BMP's") such as BMP-2, BMP-3,
- 25 BMP-4, BMP-5, BMP-6 (Vgr-1), BMP-7 (OP-1), BMP-8, BMP-9, BMP-10, BMP-11, BMP-12, BMP-13, BMP-14, BMP-15, and BMP-16. Any of BMP-2, BMP-3, BMP-4, BMP-5, BMP-6 and BMP-7; dimeric proteins such as homodimers, heterodimers, or combinations thereof, alone or together with other molecules; molecules capable of inducing an upstream or downstream effect of a BMP such as "hedgehog" proteins, or the
- 30 DNA's encoding them and any combinations thereof.

31. The system of claim 28 wherein the at least one therapeutic agent is at least one type of cellular material selected from at least one member of the group consisting of: cells of human origin (autologous or allogeneic); cells of non-human origin (xenogeneic) and any combination thereof.
- 5 32. The system of claim 31 wherein the cellular material is selected from at least one member of the group consisting of: side population cells; lineage negative cells; lineage negative CD34⁻ cells; lineage negative CD34⁺ cells; lineage negative cKit⁺ cells; mesenchymal stem cells; cord blood cells; cardiac or other tissue derived stem cells; whole bone marrow; bone marrow mononuclear cells; endothelial progenitor cells; satellite cells; 10 muscle derived cells; go cells; endothelial cells; adult cardiomyocytes; fibroblasts; smooth muscle cells; cultures of mesenchymal stem cells with 5-aza forces differentiation into cardiomyocytes; adult cardiac fibroblasts + 5-aza; genetically modified cells; tissue engineered grafts; MyoD scar fibroblasts; Pacing cells; embryonic stem cell clones; embryonic stem cells; fetal or neonatal cells; immunologically masked cells; tissue 15 engineered grafts; genetically modified cells; teratoma derived cells and any combinations thereof.
33. The system of claim 28 wherein the at least one therapeutic agent comprises at least one polymer coating, the at least one coating selected from at least one member of the group consisting of: polycarboxylic acids; cellulosic polymers, including cellulose acetate and 20 cellulose nitrate; gelatin; polyvinylpyrrolidone; cross-linked polyvinylpyrrolidone; polyanhydrides including maleic anhydride polymers; polyamides; polyvinyl alcohols; copolymers of vinyl monomers such as EVA; polyvinyl ethers; polyvinyl aromatics; polyethylene oxides; glycosaminoglycans; polysaccharides; polyesters including polyethylene terephthalate; polyacrylamides; polyethers; polyether sulfone; polycarbonate; 25 polyalkylenes including polypropylene, polyethylene and high molecular weight polyethylene; halogenated polyalkylenes including polytetrafluoroethylene; polyurethanes; polyorthoesters; proteins; polypeptides; silicones; siloxane polymers; polylactic acid; polyglycolic acid; polycaprolactone; polyhydroxybutyrate valerate and blends and copolymers thereof; coatings from polymer dispersions such as polyurethane dispersions 30 (BAYHDROL[®], etc.), fibrin, collagen and derivatives thereof; polysaccharides such as

celluloses, starches, dextrans, alginates and derivatives; hyaluronic acid; squalene emulsions; polyacrylic acid, a copolymer of polylactic acid and polycaprolactone; medical-grade biodegradable materials such as PGA-TMC, Tyrosine-Derived Polycarbonates and arylates; polycaprolactone co butyl acrylate and other co polymers; Poly-L-lactic acid
 5 blends with DL-Lactic Acid; Poly(lactic acid-co-glycolic acid); polycaprolactone co PLA; polycaprolactone co butyl acrylate and other copolymers; Tyrosine-Derived Polycarbonates and arylate; poly amino acid; polyphosphazenes; polyiminocarbonates; polydimethyltrimethylcarbonates; biodegradable CA/PO₄'s; cyanoacrylate; 50/50 DLPLG; polydioxanone; polypropylene fumarate; polydepsipeptides; macromolecules such as
 10 chitosan and Hydroxylpropylmethylcellulose; surface erodible material; maleic anhydride copolymers; zinc-calcium phosphate; amorphous polyanhydrides; sugar; carbohydrate; gelatin; biodegradable polymers; and polymers dissolvable in bodily fluids; A block copolymers; B block copolymers and any combinations thereof.

34. A system for reducing the diameter of a stent assembly comprising:
 15 a stent contracting assembly, the stent contracting assembly comprising a plurality of moveable contracting members, the plurality of contracting members defining a diameter reduction chamber, the chamber having a reduced diameter configuration and a pre-reduction diameter configuration, the stent contracting assembly constructed and arranged to receive the stent assembly into the chamber, wherein when the chamber of the
 20 stent contracting assembly is in the pre-reduction diameter configuration at least a portion of the stent assembly has a first diameter and when the chamber is in the reduced diameter configuration the at least a portion of the stent assembly has a second diameter, the second diameter being less than the first diameter;

a first mandrel, a portion of the first mandrel constructed and arranged to be
 25 positioned within the diameter reduction chamber, a first portion of the stent assembly disposed about the portion of the first mandrel; and

a protective sheath, the protective sheath
 constructed and arranged to be positioned within the diameter reduction chamber, the
 protective sheath disposed about the stent assembly, the protective sheath having a wall
 30 thickness and an inside surface, the inside surface being defined by a wall thickness pattern,

the wall thickness pattern comprising alternating thicker portions of the wall thickness and thinner portions of the wall thickness, the thicker portions extending radially inward toward the stent assembly to a greater extent than the thinner portions, a thinner portion being positioned between each thicker portion.

- 5 35. The system of claim 27 further comprising a second mandrel, a portion of the second mandrel constructed and arranged to be positioned within the diameter reduction chamber, a second portion of the stent assembly disposed about the portion of the second mandrel.

36. The system of claim 2 wherein a stent assembly engagement surface of the at least
10 one of the contracting members comprises a soft contacting region and a hard contacting region along the axis of the chamber.

37. A method for reducing the diameter of a stent assembly comprising the steps of:
providing a stent assembly, the stent assembly comprising a sheath the stent
being disposed about the sheath, the sheath having an inner diameter, the stent having a
15 proximal region and a distal region, the proximal region having a proximal region outer
diameter and the distal region having a distal region outer diameter;
reducing the distal region outer diameter from an uncrimped state to a
crimped state, wherein in the uncrimped state the distal region outer diameter is greater than
the distal region outer diameter in the crimped state;
20 reducing the proximal region outer diameter from an uncrimped state to a
crimped state, wherein in the uncrimped state the proximal region outer diameter is greater
than the proximal region outer diameter in the crimped state;
maintaining the inner diameter of the sheath at a substantially constant
diameter when reducing the distal region outer diameter and when reducing the proximal
25 region outer diameter.

38. The method of claim 37 wherein in the crimped state the proximal region outer
diameter is greater than the distal region outer diameter.